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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,152	07/23/2003	David B. Agus	67789-19	1369

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DAVIS WRIGHT TREMAINE LLP
865 FIGUEROA STREET
SUITE 2400
LOS ANGELES, CA 90017-2566

EXAMINER	
ANDERSON, JAMES D	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 08/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/625,152	AGUS, DAVID B.	
	Examiner	Art Unit	
	James D. Anderson	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 July 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9, 11-20, 22-28 and 57-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,8,9,11-14,19,20,22-24,26,27 and 57-62* is/are rejected.

7)☒ Claim(s) *4-7,15-18,25 and 28* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed July 12, 2006, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Status of the Claims

Claims 1-9, 11-20, 22-28 and 57-62 are currently pending and are the subject of this Office Action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 8-9, 11-14, 19-20, 22-24, 26-27 and 57-62 are again rejected under 35 U.S.C. § 102(e) as being anticipated by Steiner *et al.* (U.S. Patent No. 6,632,447; Issued Oct. 14, 2003; Filed Nov. 8, 2000).

Steiner *et al.* teach the use of antiestrogens, including raloxifene, for the prevention and treatment of prostate cancer (Abstract; Claims; col. 4, lines 7-8). The compositions for the prevention or treatment of prostate cancer can be administered in a range of 5 to 80 mg/day (col. 6, lines 18-19) and can be administered orally (col. 6, lines 27-29).

Applicant's arguments have been fully considered but they are not persuasive. Applicants argue, *inter alia*, that "prostate cancer" as used by Steiner *et al.* does not refer androgen-independent prostate cancer (AIPC). This is not persuasive because applicants are attempting to limit the disclosure of Steiner *et al.* to a narrow definition of prostate cancer without support for such a narrow definition. One skilled in the art would appreciate that "prostate cancer", when used in Steiner, includes both androgen-dependent and androgen-independent prostate cancer. Steiner *et al.* recognize the two types of prostate cancer wherein they state:

> Hormone therapy remains the standard method of treatment of recurrent and advanced prostate cancer despite the common development of hormone refractory disease. Therefore, new approaches for the prevention and treatment of prostate cancer are needed to accommodate the increasing number of men diagnosed with the disease. Steiner et al., Column 14, Lines 9-15.

Thus, the skilled artisan has no reason to believe that Steiner does not contemplate the treatment of AIPC in the methods described therein.

Applicants further argue that "treat" or "treatment" used in Steiner *et al.* does not include the methods of the instant application. This is not persuasive. Steiner clearly teaches the treatment of prostate cancer, including AIPC (as discussed *supra*). Steiner teaches that the

chemopreventative agent prevents, prevents reoccurrence of, suppresses and inhibits prostate carcinogenesis but also treats prostate cancer (Abstract). Clearly, treating prostate cancer is a separate concept in Steiner, not meant to be commensurate with prevention as applicants assert. Further evidence of this is found in column 3, lines 1-6 of Steiner wherein it is taught that:

> This invention relates to a method of treating a subject *with* prostate cancer comprising: administering to a mammal subject, a pharmaceutical preparation comprising an anti-estrogen, or its analog, derivative, isomer, and metabolite thereof, and their pharmaceutically acceptable salts, esters, or N-oxides, and mixtures thereof.

Clearly, "a subject with prostate cancer" is in need of a treatment, not prevention. Again, applicants are attempting to limit the disclosure of Steiner *et al.* to only the prevention of prostate cancer when it is clear that the reference contemplates the treatment of prostate cancer. Column 5, line 17 also discusses the "treatment of prostate cancer". A "method of treating a subject with prostate cancer" is taught in Claim 2 (col. 17, lines 9-14). Clearly, this is not a method of preventing prostate cancer as applicants assert. The patient already has prostate cancer and is being treated with a selective estrogen modulator, "thereby treating the subject with prostate cancer." Although the examples in Steiner are limited to the prevention of prostate cancer, one skilled in the art would appreciate that treatment of prostate cancer taught in Steiner *et al.* would include stabilizing or reducing primary tumor mass.

Upon further consideration, however, Steiner *et al.* only define a limited range of doses (*i.e.* 5-80 mg/day) and do not teach the administration of an antiestrogen further comprising an

estrogen-lowering drug. As such, instant claims 4-7, 15-18, 25 and 28 have been removed from this rejection as not being anticipated by the Steiner *et al.* reference.

Claim Rejections - 35 USC § 103

In view of applicant's arguments, the rejection of claims 1-9, 11-20 and 22-28 under 35 U.S.C. § 103 as being unpatentable over Lau *et al.* in view of Neubauer *et al.* is hereby **withdrawn**.

Although the prior art appreciates the fact that estrogen receptor β is expressed in prostate cancer cells (as evidenced by Lau *et al.*), the Neubauer reference would only support a *prima facie* case of obvious if the instantly claimed methods were drawn to inhibiting metastases of primary prostate cancer tumors. Raloxifene, in the doses used in the Neubauer reference, were ineffective at inhibiting primary tumor growth.

As such, given the combined teachings of Lau *et al.* and Neubauer *et al.*, the skilled artisan would not have a reasonable expectation that raloxifene could inhibit AIPC tumor growth at the doses instantly claimed. This is especially true given that the doses instantly claimed are less than or equal to the doses administered in the Neubauer reference.

Allowable Subject Matter

Claims 4-7, 15-18, 25 and 28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Claims 1-3, 8-9, 11-14, 19-20, 22-24, 26-27 and 57-62 are rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James D. Anderson whose telephone number is 571-272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

James D. Anderson
Patent Examiner
AU 1614

August 4, 2006

Ardin H. Marschel 8/17/06
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER